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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,569	03/09/2001	Michael Girouard	06-2916.485	6328

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KCI
4958 Stout Drive
P.O. Box 659508
San Antonio, TX 78265-9508

EXAMINER

PORTER, RACHEL L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,569

Applicant(s)

GIROUARD ET AL.

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 16 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 3/9/01. Claims 1-20 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

It does not identify the citizenship of each inventor.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

In particular, two of the named inventors (Michael Wells and Michael Girouard) have not signed the declaration or provided information residence, citizenship, and mailing/post office address.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20 recite a system in the preamble, but recite a series of steps in the body of the claim. It is unclear as to which statutory class of invention the applicant intends to claim, since "system" claims are generally interpreted as apparatus-type claims which recite a series of components, while process or method claims recite a series of steps.

Claim 5 recites "said alarm limits are set at medically meaningful levels." It is unclear to the Examiner how this limitation further defines the features of claim 4 since it is unclear what the phrase "medically meaningful" means or what criteria are included within this threshold. For the purpose of applying art, the Examiner will interpret the use of any alarm/warning as an alarm or warning that has been set to a medically significant level.

Claim 20 recites "[a] system according to claim 19 wherein an intermediate treatment goal for a selected treatment routine for said wound of said patient;...". It is unclear to the Examiner how this claim further defines claim 19. In particular, it appears this part of the claim is missing a word or an additional phrase to describe the "intermediate treatment."

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, claim 1-20 only recites an abstract idea. The recited steps of merely obtaining information about a patient and a patient's wound and performing an analysis to determine the best treatment does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to select a medical treatment over another.

As to technological arts recited in the preamble, mere recitation in the preamble (i.e., intended or field of use) or mere implication of employing a

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machine or article of manufacture to perform some or all of the recited steps does not confer statutory subject matter to an otherwise abstract idea unless there is positive recitation in the claim as a whole to breathe life and meaning into the preamble. In the present case, none of the recited steps are directed to anything in the technological arts as explained above with the exception of the recitation in the preamble that the method is "automated". Looking at the claim as a whole, nothing the body of the claim recites any structure or functionality to suggest that a computer performs the recited steps. Therefore, the preamble is taken to merely recite a field of use.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed method select appropriate wound treatments and is therefore useful, tangible and concrete.

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-20 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,2,7-14 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dormond et al (4,839,822--Dormond).

[claim 1] Dormond discloses an automated data processing system comprising the steps of:

- comparing patient characteristics with a patient data set and obtaining a result therefrom; (Figure 11; col. 6, line 39-col. 7, line 10)
- comparing wound characteristics with a wound characteristics data set and obtaining a result therefrom; and (col. 5, lines 19-34;46-54)
- comparing said patient characteristic result and said wound characteristic result with indicia connected to a library of treatment routines to generate a proposed treatment routine. (col. 6, lines 32-54; col. 7, line 63-col. 8, lines 19)

[claim 2] Dormond teaches a comprising also establishing intermediate treatment goals for a selected treatment routine for said wounds of said patient. (col. 9, lines 7-10; Figure 18—e.g. goals are divided into categories)

[claim 7] Dormond discloses a system according to wherein the selection of a treatment routine generates a desired data output. (Figure 18; col. 9, lines 45-60)

[claim 8] Dormond teaches an automated data processing system comprising the steps of:

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- comparing patient characteristics with a patient data set and obtaining a result therefrom; (Figure 11; col. 6, line 39-col. 7, line 10)
- comparing wound characteristics with a wound characteristics data set and obtaining a result therefrom; (col. 5, lines 19-34;46-54)
- comparing said patient characteristic result and said wound characteristic result with indicia connected to a library of treatment routines to generate a selection of proposed treatment routines; (col. 6, lines 32-54; col. 7, line 63-col. 8, lines 19)
- evaluating the selected proposed treatment routines in relation to selected criteria; and (col. 17, lines 3-28)
- generating output wherein said proposed treatment routines are ranked in relation to said criteria (col. 17, lines 38-44)

[claims 9-13] Dormond teaches a system according to claim 8 wherein said criteria may be adjusted. (col. 17, lines 26-34—the weighting is variable)

[claim 14] Dormond teaches a system according to claim 12 wherein an intermediate treatment goal for a selected treatment routine for said wounds of said patient is created. (col. 9, lines 7-10; Figure 18—e.g. goals are divided into categories)

[claim 19] Dormond teaches an automated data processing system comprising the steps of:

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- comparing patient characteristics with a patient data set and obtaining a result therefrom;
- comparing wound characteristics with a wound characteristics data set and obtaining a result therefrom;
- updating said data sets with more recent data as desired thereby creating current data sets; (col. 10, lines 7-18—method includes several file update features)
- determining the most current data set for data; (col. 10, lines 7-18—method includes several file update features)
- updating the patient data result using the most current patient data set;(col. 7, lines 54-62)
- updating the wound characteristic result using the most current wound data set; (col. 13, lines 31-40)
- comparing said patient characteristic result and said wound characteristic result with indicia connected to a library of treatment routines to generate a selection of proposed treatment routines; (col. 6, lines 32-54; col. 7, line 63- col. 8, lines 19)
- evaluating the selected proposed treatment routines in relation to selected criteria; (col. 17, lines 3-28)
- generating output wherein said proposed treatment routines are ranked in relation to said criteria. (col. 17, lines 38-44)

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-6,15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormond as applied to claims 1,8, and 19 above, and further in view of Douglas (USPN 6,039,688).

[claim 3] Dormond discloses a system for wound treatment wherein intermediate or sub goals are established (Figure 18) but does not expressly disclose monitoring the patient as they progress from the commencement of a treatment program throughout various goals (i.e. intermediate goals.) Douglas teaches a system that monitors patient progress as they reach different milestones (i.e. intermediate goals). (col. 9, lines 23-38; col. 10, lines 27-39) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Dormond with the teaching of Douglass to track patient progress through intermediate goals of treatment. As suggested by Douglass, one would have been motivated to include this feature to allow the treating healthcare provider to determine if the patient is progressing or if the program needs to be modified. (col. 10, lines 49-57).

[claims 4-6] Dormond discloses a system for wound treatment wherein

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intermediate or sub goals are established (Figure 18), but does not expressly disclose monitoring the patient as they progress from the commencement of a treatment program throughout various goals (i.e. intermediate goals.) and does not teach using alarms to track a patient's progress. Douglas teaches a system that monitors patient progress, using alarms that are triggered under various medically meaningful conditions (col. 10, lines 17-40) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Dormond with the teaching of Douglass to track patient progress through intermediate goals of treatment and alarms. As suggested by Douglass, one would have been motivated to include this feature to allow the treating healthcare provider to determine if the patient is progressing or if the treatment program needs to be modified. (col. 10, lines 49-57).

[claims 15-17] The limitations of claims 15-17 are substantially similar to those recited in claim 3-6. As such, the limitations claims 15-17 are addressed by the rejections of claims 3-6 and 8, and incorporated herein.

[claim 18] Dormond teaches the wound treatment system according to claim 9, but does not expressly disclose that financial criteria are considered. Douglas discloses a system wherein financial criteria may also be input and financial output may be generated for healthcare providers, payers and patients. (col. 19, lines 22-col. 20, line 5) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Dormond

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with the teaching of Douglas to allow a financial analysis to be done on the treatment options. As suggested by Douglas, one would have been motivated to include this feature to assess the benefits of participating in the system versus considering other treatment options (col. 19, line 39-44)

[claim 20] The limitations of 20 are substantially similar to those recited in claim 3-6. As such, the limitations claim 20 are addressed by the rejections of claims 3-6 and 19, and incorporated herein.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

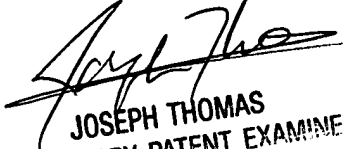
- Shaibani (USPN 5,586,024) teaches a system and method for diagnosis of trauma injuries.
- Martin et al (USPN 6,484,144) discloses a system for planning treatment options.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP
RP

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER